EXHIBIT A

COPY

TO THE MERCANTILE COURT OF MADRID

PLAINTIFF

PLAINTIFF: ETHYPHARM, S.A.

SOLICITOR: Ms. ALMUDENA GALÁN GONZÁLEZ

ATTORNEY: Mr. ANTONIO CASTÁN PÉREZ-GÓMEZ

DEFENDANT

LABORATORIOS BELMAC, S.A.

PROCEDURE ORDINARY SUIT

OBJECT VIOLATION OF PATENT RIGHTS

FACTS

FIRST.- THE PLAINTIFF COMPANY ETHYPHARM, S.A. AND THE GLOBAL BASIS OF THE SUIT THAT IS BEING FILED

SECOND.- THE INVENTION PATENT NO. 9301319 THAT SERVES AS THE BASIS OF THE SUIT

THIRD.- THE COMMERCIAL RELATIONS BETWEEN THE PARTIES REGARDING OMEPRAZOL MANUFACTURED ACCORDING TO PATENT NO. 9301319

A) The defendant LABORATORIOS BELMAC, S.A.

B) The agreement signed by LABORATORIOS BELMAC, S.A. and ETHYPHARM, S.A. for the manufacture of Omeprazole according to patent ES 9301319

C) The machinery owned by ETHYPHARM, S.A., installed at the LABORATORIOS BELMAC, S.A. factory for the production of Omeprazole according to patent ES 9301319

D) The explicit recognition by LABORATORIOS BELMAC, S.A. of the technology inherent in patent ES 9301319 held by ETHYPHARM, S.A and of the business effort made by the plaintiff at the defendant's plant

E) The Omeprazole manufactured by LABORATORIOS BELMAC, S.A. under the patent belonging to ETHYPHARM, S.A.

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B) The negotiations commenced and the commitment undertaken by LABORATORIOS BELMAC, S.A. to cease all exploitation of the patent and machinery of ETHYPHARM, S.A. after 23rd March 2002

C) The final removal, after several attempts to do so, of ETHYPHARM S.A.'s machinery in September 2003

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A) The appearance on the market of Omeprazole products manufactured by LABORATORIOS BELMAC, S.A. after 23rd March 2002

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B) The fact verification proceedings carried out in Zaragoza at the LABORATORIOS BELMAC, S.A. plant, on 19th December 2002

C) The technical verification of the infringement: expert's report provided on the documentation seized in Zaragoza

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B) Quantification of the damages from the manufacture and sale of Omeprazole from 23rd March 2002 onwards

GROUNDS OF LAW

-I-

BASES OF TRIAL

1. Jurisdiction and nature of trial
2. Objective competency
3. Territorial competency
4. Legitimation
5. Postulation
6. Probatory Activity

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-II-

RIGHTS DERVIED FROM THE PLAINTIFF'S OWNERSHIP OF THE PATENT ES 9301319 AND INFRINGEMENT OF SAME IN THE MANUFACTURE AND SALE OF OMEPRAZOL BY THE DEFENDANT

1.- Notion and regulation for patent

2 - Scope of the right to exclusiveness in the case of *product* patents

3.- Infringement of a patent *by equivalence*

4.- Lack of any virtue in possible allegation to the contrary based on LABORATORIO BELMAC, S.A.'s patent no. 2192929: articles 55 and 56 may be invoked for this purpose

-III-

ACTIONS TO WHICH THE HOLDER OF THE PATENT RIGHTS IS ENTITLED

1.- General regime

2.- Intention to restitution

3.- Proof of damages

-IV-

IMPOSITION OF COSTS

TO THE MERCANTILE COURT OF MADRID

I, Ms. ALMUDENA GALÁN GONZÁLEZ, Solicitor of the Courts, on behalf of the company ETHYPHARM, S.A., with address in Madrid at Calle Marqués de la Ensenada no. 16, whose representation I accredit by way of a power of attorney that is attached in the proper form, with the assistance of Attorney ANTONIO CASTÁN PÉREZ-GÓMEZ, appear before the Court and, as prescribed by the Law, STATE:

That by way of this writ and with the powers of representation I wield, I file an ORDINARY SUIT for the violation of patent rights against LABORATORIOS BELMAC, S.A., with address at Calle Teide 4, 1 Parque Empresarial La Marina 28700 San Sebastián de los Reyes (Madrid).

As a foundation for the suit I provide the following:

FACTS

ONE.- THE PLAINTIFF COMPANY ETHYPHARM, S.A. AND THE OVERALL BASIS OF THE SUIT THAT IS BEING FILED

The purpose of this suit is the full restitution of the patent rights of the company ETHYPHARM, S.A. for the technology inherent to invention patent number 9301319, which covers a "*Stable formulation of microgranules of Omeprazole and a procedure for obtaining them which was being used.*" As we shall make clear in this writ, the defendant, LABORATORIOS BELMAC, S.A., after having maintained commercial relations with ETHYPHARM, S.A. for the manufacture

and sale of Omeprazole under the aforementioned patent, put an end to said relationship and continued to make use of the patented formulation to its own benefit.

The plaintiff, ETHYPHARM, S.A., is the Spanish affiliate of a leading firm in the development of pharmaceutical solutions. With a staff of more than 800 employees all over the world, ETHYPHARM has 5 Centres of Research and 3 factories in France, once Centre of Research in Canada, subsidiaries in India and China and presence in countries such as Japan, Italy or the United States. Over the years, ETHYPHARM, S.A. has developed and launched approximately 50 products in more than 70 countries and is acknowledged as one of the leading companies in pharmaceutical technology.

We attach as DOCUMENT NO. 1 the paper print-out of the information that may be obtained on the ETHYPHARM group from its website on the Internet www.ethypharm.com.

TWO.- THE INVENTION PATENT NO. 9301319 THAT SERVES AS THE BASIS FOR THE SUIT

A) The plaintiff is the registered owner of Spanish patent application number 9301319 and publication number 2052458. We shall refer hereinafter to the plaintiff's title under the reference patent ES 9301319. This patent was applied for on 15th June 1993 and granted by resolution on 5th December 1994. The claims that define the object of this patent are as follows:

"1. Stable formulation of microgranules of omeprazole that are composed of a neutral nucleus of sugar and starch, characterised by having an active layer formed by a dilution of omeprazole in mannitol in perceptively quantities.

2. Formulation according to the 1st claim, characterised by the fact that a perceptible 10% of the weight of the active layer of omeprazole is carboxymethyl starch.

3. Formulation according to the 2nd claim, characterised by the fact that a perceptible 5% of the active layer of omeprazole is a tensioactive compound of the sodium laurylsulphate type.

4. Formulation according to all of the claims 1 to 3, characterised by the fact that the surface of the active layer of omeprazole has a complementary protective layer of mannitol.

5.Formulation according to all of the claims 1 to 4, characterised by the fact that the omeprazole dilution in mannitol and the aforementioned protective layer are applied using a highly viscous binding agent such as hydroxypropylmethylcellulose.

6. Formulation according to all of the claims 1 to 5, characterised by the fact that the active granules have an outer layer for gastric protection composed by a gastro-resistant coating such as hydroxypropylmethylcellulose phthalate and talc.

7.Procedure for obtaining the formulation according to all of the claims 1 to 6, characterised by the fact that a dry dilution of mannitol and omeprazole is applied to the neutral granules composed of sugar and starch using a highly viscous binding solution such as hydroxypropylmethylcellulose in solution, in a mix of at least 80% of ethanol and 20% of water at the most.

8. Procedure according to claim 7, characterised by the fact that each application of the dilution is then dried, at a temperature of between 35° C and 40°C for a duration that allows to bring down the content of active microgranules in water to 1% and the ethanol content to 2,000 ppm.

9. Procedure according to claims 7 and 8, characterised by the use of neutral microgranules measuring between 0.7 and 0.9 mm.

10. Procedure according to claims 7, 8 and 9, characterised by the use of flat-bottomed turbines to apply the active dilution and the gastro-protective coatings.

We attach as DOCUMENT NO. 2, the certification accrediting the ownership and validity of the patent ES 9301319 belonging to ETHYPHARM, S.A. and as DOCUMENT NO. 3, the official certificate issued by the Spanish Patents and Trademarks Office with the text for the said patent.

B) The patent held by ETHYPHARM, S.A. includes ten claims. Claims 1 to 6 refer to a pharmaceutical formulation or product; claims 7 to 10 refer to the procedure for preparing or obtaining this formulation. The essential characteristic of the first group of claims is that the stable formulation of Omeprazole microgranules is composed of a neutral nucleus composed of sugar and starch covered by an active layer formed by a dilution of Omeprazole in mannitol in perceptibly equal quantities.

THIRD.- THE COMMERCIAL RELATIONS MAINTAINED BETWEEN THE PARTIES REGARDING THE OMEPRAZOL MANUFACTURED ACCORDING TO PATENT NO. 9301319

A) The defendant LABORATORIOS BELMAC, S.A.

The suit is directed against the company LABORATORIOS BELMAC, S.A. This firm was set up in 1991. Its main office is located in San Sebastián de los Reyes (Madrid) and its main factory is situated in Zaragoza. As may be seen from its website www.belmac.com, the defendant's activity is focused on products acting on the digestive system.

We attach as DOCUMENT NO. 4 the paper print-out of the information that may be obtained on the defendant on this page; and as DOCUMENT NO.5, a simple informative note on LABORATORIOS BELMAC, S.A., obtained from the Central Companies Register.

B) The agreements signed by LABORATORIOS BELMAC, S.A. and ETHYPHARM, S.A. for the manufacture of Omeprazole according to patent ES 9301319

In order to manufacture Omeprazole in Spain, ETHYPHARM, S.A. established commercial relations with the firm LABORATORIOS BELMAC, S.A.. By virtue of the agreements signed in this regard, the defendant undertook a commitment with the plaintiff to manufacture on an exclusive basis for ETHYPHARM, S.A. the Omeprazole ordered from my client and also to purchase from ETHYPHARM, S.A. the Omeprazole ordered from its own customers. The reason was very simple: my client provided LABORATORIOS BELMAC, S.A. with the necessary technological equipment to manufacture Omeprazole according to patent ES 9301319.

As proof of the foregoing and DOCUMENT NO. 6, we attach the manufacture contract of 23rd March 2000 and the purchase commitment contract of the same date formalising the grounds of the commercial relation that ETHYPHARM, S.A. and LABORATORIOS BELMAC, S.A. had maintained over the years.

Both of these documents are signed on behalf of LABORATORIOS BELMAC, S.A. by Mr. Adolfo Herrera, General manager of the company.

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In the first agreement, LABORATORIOS BELMAC, S.A. undertook the commitment to "*manufacture and deliver the product manufactured at its facilities, detailed in the Appendix, following reception of the order from ETHYPHARM, S.A.*". The Appendix contains reference to

"Microgranules of Omeprazole, according to patent no. 9207249"

As may be seen in Document no. 3 attached hereto, this number corresponds to the French patent, which has priority over the Spanish.

In the purchase commitment letter, LABORATORIOS BELMAC, S.A. undertakes the following commitment:

> *"To purchase on an exclusive basis from ETHYPHARM its own needs and those of its customers, as long as ETHYPHARM guarantees such supply, in the timeframe and form established in the orders, at competitive market prices and that the product (microgranules of Omeprazole) is manufactured by BELMAC on its own premises".*

C) The machinery owned by ETHYPHARM, S.A. installed at the LABORATORIOS BELMAC, S.A. factory for the production of Omeprazole according to patent no. ES 9301319

In order to facilitate the production of Omeprazole according to ETHYPHARM, S.A.'s own technology, my client provided the necessary machinery to LABORATORIOS BELMAC, S.A. at its own Zaragoza plant. In this regard, we hereby attach:

- As <u>DOCUMENT NO.7,</u> the sworn statement from LABORATORIOS BELMAC, S.A. dated 6th November 1992, with the signature of its then General Manager, Mr. Ángel Pérez de Ayala, which acknowledged, among other facts, the following:

" 1. That LABORATORIOS BELMAC, S.A. is negotiating with ETHYPHARM, S.A. the signing of a manufacture and collaboration contract as part of the line of contract projects and relations that both parties have been preparing an developing in recent months.

2. That parallel to these negotiations and during the course of the latter, ETHYPHARM has at its own cost carried out work and installations within part of the building owned by LABORATORIOS BELMAC, S.A. located at Polígono de Malpica Calle C, no. 4 (Zaragoza). The cost of the installations and adaptations carried out to date reaches a total figure of 27,119,843 Ptas. plus the corresponding VAT.

Similarly, ETHYPHARM has installed machinery that is identified and recognised by LABORATORIOS BELMAC, S.A. as also being entirely and totally owned by the former entity and included in this list that accompanies this document".

- As <u>DOCUMENT NO. 8,</u> the list of the machinery owned by ETHYPHARM, S.A. and the photograph of the room where part of this machinery was placed.

D) <u>The explicit recognition by LABORATORIOS BELMAC, S.A. of the technology inherent in patent ES 9301319 held by ETHYPHARM, S.A and of the business effort made by the plaintiff at the defendant's plant</u>

The assistance given by ETHYPHARM, S.A. to LABORATORIOS BELMAC, S.A. afforded the latter its commercial take-off, due to its specialisation in the manufacture and sale of Omeprazole according to ETHYPHARM, S.A.'s technology. The documents attached hereto prove the extent to which LABORATORIOS BELMAC, S.A. received the necessary means for carrying out its industrial activity from ETHYPHARM, S.A.

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- As DOCUMENT NO. 9, we attach the letter of 20th March 1991 from Mr. Clemente González Azpeitia, acknowledging, among other things, the following:

  "The truth is that our personnel, with the inestimable collaboration of Mr. Bernabé, are day by day adapting better to the characteristics of the new machinery and that gradually, the quality of the Omeprazole pellets is greatly improving".

- As DOCUMENT NO. 10, the statement signed by LABORATORIOS BELMAC, S.A. on 2nd March 1998m certifying the following:

  "ETHYPHARM has entered into a manufacture agreement with LABORATORIOS BELMAC, S.A.

  ETHYPHARM owns the manufacture method, the technology and the machinery used for the process of manufacturing the batches of Omeprazole. LABORATORIOS BELMAC, S.A. is authorised to use this machinery and to use the know-how for ETHYPHARM's customers.

  LABORATORIOS BELMAC, S.A. is audited on a regular basis by ETHYPHARM to ensure that the GMP is followed according to ERHYPHARM's requirements".

- As DOCUMENT NO. 11, the sworn statement from LABORATORIOS BELMAC, S.A., dated 2nd October 1998, as follows:

  "ETHYPHARM has sent BELMAC samples of the product:

- *20 mg Capsules of omeprazole (water-based formula).*

These samples are delivered with the sole objective that Laboratorios Belmac, S.A., may first verify the quality of the product.

For a period of 10 (ten) years following the date of this agreement, BELMAC undertakes to keep secret the results of the analysis and the existence of these samples, and to send these results only to collaborators and advisers that are also found by professional secrecy".

E) The Omeprazole manufactured by LABORATORIOS BELMAC, S.A. under the patent belonging to ETHYPHARM, S.A.

For the duration of the commercial relations between the parties, LABORATORIOS BELMAC, S.A. was manufacturing Omeprazole under patent no. ES 9301319 and using ETHYPHARM's machinery for the plaintiff's customers (Omeprazole Cinfa, from LABORATORIOS CINFA, S.A. and Omeprazole Leciva, from LABORATORIOS LECIVA, S.A.) and for its own customers (Belmazol, from the same LABORATORIOS BELMAC, S.A.;) Ulcometión, from LABORATORIOS FARMA; Omeprazole Davur, from LABORATORIOS DAVUR, S.L.; Omeprazole Acyfabrik, from LABORATORIOS ACYFABRIK, S.A. and Omeprazole FARMIGEL, from LABORATORIOS FARMIGEL, S.A.). As regards this Omeprazole manufactured in the past by LABORATORIOS BELMAC, S.A., we hereby attach the following:

- As DOCUMENT NO. 12, a complete dossier or protocol for the manufacture of the speciality Omeprazole for each of the batches manufactured by LABORATORIOS BELMAC, S.A. in March 2001 for ETHYPHARM, S.A.. This dossier contains the final balance indicating the manufacture formula.

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- As DOCUMENT NO. 13, the technical records corresponding to the marketing authorisations granted by the Spanish Medicine Agency for the specialities Belmazol 20 mg. (first authorisation 1993, revised in 2001) and Omeprazole Cinfa 20 mg. (approved in May 2000). Both contain the basic formulation that corresponds in essence with ETHYPHARM S.A.'s patent.: "*Sucrose, corn starch, mannitol, sodium carboxymethylstarch, sodium laurylsulphate, povidone, hypromellosa, hypromellosa phthalate, partially hydrogenated soya oil, talc*".

- As DOCUMENT NO. 14, for example purposes, a copy of the two production agreements entered into by LABORATORIOS BELMAC, S.A. with two other laboratories for the manufacture of Omeprazole. These agreements expressly state that " *the said microgranules have been manufactured under ETHYPHARM's patent and technology*".

FOURTH.- THE UNILATERAL INTERRUPTION OF COMMERCIAL RELATIONS BY LABORATORIOS BELMAC, S.A.

A) Termination of the manufacture contract in November 2001 by LABORATORIOS BELMAC, S.A.

In November 2001, LABORATORIOS BELMAC, S.A. decided to unilaterally terminate the manufacture contract entered into by the parties, with effect as from 23rd March 2002. We attach as DOCUMENT NO. 15 the letter sent on 14th November 2001 by LABORATORIOS BELMAC, S.A. to ETHYPHARM, S.A, announcing the termination of the manufacture contract.

B) The negotiations commenced and the commitment undertaken by LABORATORIOS BELMAC, S.A. to cease all exploitation of the patent and machinery of ETHYPHARM, S.A. after 23rd March 2002

Obviously, the decision by LABORATORIOS BELMAC, S.A. to unilaterally terminate the contract gave rise to the corresponding conflict between the parties. Please remember that the letter received by ETHYPHARM,S.A. implied, on the one hand, that my client could not meet the orders it had already received from its customers; and on the other hand, that LABORATORIOS BELMAC, S.A. intended to continue manufacturing Omeprazole according to ETHYPHARM, S.A.'s technology and machinery for its own benefit and without having to purchase the latter from the plaintiff. The negotiations started in this regard led to the following commitment:

(a) LABORATORIOS BELMAC, S.A. would meet the orders from ETHYPHARM, S.A. that had already been accepted prior to the termination.

(b) The machinery owned by ETHYPHARM, S.A and granted to LABORATORIOS BELMAC, S.A., would be used exlcusiveley to manufacture the orders for Omeprazole from ETHYPHARM, S.A.

(c) LABORATORIOS BELMAC, S.A. would cease after 23rd March 2002 from any manufacture of Omeprazole for itself and its own customers, inasmuch as the authorisation from ETHYPHARM, S.A. to exploit patent no. 9301319 was also considered to have been repealed; and

(d) As the activity of LABORATORIOS BELMAC, S.A. regarding Omeprazole would necessarily be reduced, ETHYPHARM S.A. would proceed to gradually remove the mahcinery it had granted.

Thus, from 23rd March 2002, LABORATORIOS BELMAC, S.A. could only manufacture batches of Omeprazole for ETHYPHARM S.A.'s customers. The brands corresponding to these batches were as follows:

- Omeprazole CINFA from LABORATORIOS CINFA, S.A.

- Omeprazole LECIVA from LABORATORIOS LECIVA, S.A.

We attach as proof of the foregoing:

- As DOCUMENT NO. 16, the letter dated 18th April 2002 from ETHYPHARM, S.A. to LABORATORIOS BELMAC, S.A. specifying that after the break-up in the contractual relationship, the machinery owned by my client could only be used to manufacture its own orders and that any activity carried out by LABORATORIOS BELMAC, S.A. with Omeprazole other than in strict compliance with these orders would constitute a violation of patent ES 9301319.

- As DOCUMENT NO. 17, the letter dated 31st May 2002 from ETHYPHARM, S.A. to LABORATORIOS BELMAC, S.A. expressing its concern about the possible manufacture by these laboratories of Omeprazole for its own customers, thus violating the patent in question.

- As DOCUMENT NO. 18, the letter dated 10th June 2002 from LABORATORIOS BELMAC, S.A. undertaking the commitment to meet the pending orders using the machinery owned by ETHYPHARMA, S.A. solely to manufacture same.

C) The final removal, after several attempts to do so, of ETHYPHARM S.A.'s machinery in September 2003

Once the pending orders for Omeprazole placed by ETHYPHARM, S.A. had been completed, my client wished to remove the machinery from LABORATORIOS BELMAC, S.A. in order to prevent the defendant from continuing to use it, which would infringe the rights of the former. The following attached documentation serves as sufficient proof of the setbacks suffered by ETHYPHARM, S.A. until the machinery was returned:

- As DOCUMENT NO. 19, we attach the letter dated 11th June 2002 from ETHYPHARM, S.A. annoucning the imminent removal of the machinery in question.

- As DOCUMENT NO. 20, a selection of the correspondence exchanged between the parties in the month of September regarding the refusal by LABORATORIOS BELMAC, S.A. to allow the removal of this machinery due to supposed technical inconveniences

- As DOCUMENT NO. 21, the notary instrument issued by the Notary of Zaragoza Mr. Juan Miguel Belloch Fernández de Palencia on 12th September 2002 attesting to the refusal by LABORATORIOS BELMAC, S.A. to allow the technicians and removal staff of ETHYPHARM, S.A. to access its factory in order to remove the latter's machinery.

- As DOCUMENT NO. 22, the letter from LABORATORIOS BELMAC, S.A. ratifying its position that the machinery may not be removed before 14th October 2002.

- As DOCUMENT NO. 23, the agreement signed by the parties on 9th September 2003 reflecting the disassembly and removal of ETHYPHARM, S.A.'s machinery between 19th August 2003 and the aforementioned date. In this agreement, the parties obviously acknowledged that *"there are no claims regarding the removal of the machinery and the repair of the facilities"*.

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In other words, LABORATORIOS BELMAC, S.A. was able to continue using the said machinery for its own interests between 23rd March 2002 and 19th August 2003.

FIFTH.- THE UNCONSENTED EXPLOITATION BY LABORATORIOS BELMAC, S.A. OF ETHYPHARM S.A.'s PATENT AND TECHNOLOGY BETWEEN 23RD MARCH 2002 AND 19TH DECEMBER 2002

(A) The appearance on the market of Omeprazole products manufactured by LABORATORIOS BELMAC, S.A. after 23rd March 2002

My client very soon realised that the reason why LABORATORIOS BELMAC, S.A. had terminated the contract was none other than in order to continue manufacturing Omeprazole using the patent and technology owned by ETHYPHARM, S.A. without the need to purchase them from the plaintiff. In this regard, we attach as DOCUMENT NO. 24, a photocopy of the selection of Omeprazole pharmaceutical products manufactured by LABORATORIOS BELMAC, S.A. that this party found in the market in October 2002. From the best-before dates on these batches of Omeprazole, it is obvious that they had been manufactured after 23rd March 2002.

The table referring to these products is as follows:

Trademark	Laboratory	Batch	Best Before	Manufactured
Belmazol	BELMAC, S.A.	S 12	07 2005	July 2002
Ulcometion	ANTIBIÓTICOS FARMA, S.A.	S 07	07 2005	July 2002
Omeprazole Davur	LABORATORIOS DAVUR, S.L.	S 30	07 2004	July 2002
Omeprazole Acyfabrik	LABORATORIOS ACYFABRIK, S.A.	S 05	07 2004	July 2002
Omeprazole Farmygel	LABORATORIOS FARMYGEL, S.A.	S 14	09 2004	September 2002

The following explanations are expressly provided:

(a) That the letter "S" contained on the batch refers to the year of manufacture 2002.
(b) That the latest best-before date normally allowed for this type of pharmaceutical specialities, in the case of branded products (Belmazol and Ulcometion), is three years: therefore, if these batches carry "07 2005" as the best-before date, they were manufactured in July 2002.
(c) That the latest best-before date normally allowed for this type of pharmaceutical specialities, in the case of generic medicines (Omeprazole Davur, Omeprazole Acyfabrik and Omeprazole Farmygel) is two years: therefore the batches whose best-before date is 2004 were manufactured in 2002, in the month indicated on the side.

The conclusion to be reached here is quite clear: LABORATORIOS BELMAC, S.A. was taking advantage of the resources and technology provided by ETHYPHARM, S.A. and manufacturing its own Omeprazole for third-party companies, using the latter's own machinery and patent to do so.

B)The fact verification proceedings carried out in Zaragoza at the LABORATORIOS BELMAC, S.A. plant, on 19th December 2002

In order to verify if LABORATORIOS BELMAC, S.A. was still making use of the formulation claimed in the invention patent no. ES 9301319 and if it was still continuing to manufacture

Omeprazole for third parties using ETHYPHARM, S.A's machinery, the latter requested that preliminary proceedings be practised at the defendant's plant in Zaragoza. The following aspects should be highlighted from the substantiation and resolution of the said proceedings:

(a) The application for fact verification proceedings was admitted by the Court of First Instance no. 72 of Madrid in Instrument of 5th November 2002. The Court's decision contains the authorisation for Mr. Domingo Bernabé from ETHYPHARM, S.A. to act as *practicum* in these proceedings and the appointment as expert of Mr. Rafael Sánchez Guillermo, in possession of a Degree in Pharmacy. The Court agreed that the proceedings be carried out by means of letters rogatory.

(b) The Court of First Instance no. 14 in Zaragoza carried out the proceedings at the factory and offices of LABORATORIOS BELMAC, S.A., at Malpica Industrial Estate on 19th December 2002 after 11.00 o' clock a.m. Mr. Rafael Sánchez Guillermo, as the independent expert, Mr. Domingo Bernabé, as practicum for ETHYPHARM, S.A. and the undersigning solicitor participated in the proceedings. The Legal Secretary issued the corresponding handwritten instrument, which was later transcribed to computerised format. After the proceedings had been carried out, the reports were sent back to the Court of First Instance in Madrid.

(c) ETHYPHARM, S.A. immediately requested that the Court of First Instance in Madrid deliver the judicial evidence needed to prepare the main suit. LABORATORIOS BELMAC, S.A., however, came before the Court of First Instance no. 72 of Madrid to oppose delivery of this evidence, thus causing the corresponding incident. The Hearing was held on 3rd February 2003 and the incident was settled by Court Instrument of 19th January 2005, notified on 10th February of this year.

The Court of First Instance no. 72 of Madrid did not accept the opposition and ordered that the evidence be delivered to my client.

These points are proven by the following attached documents:

- As DOCUMENT NO. 25, a copy of the document applying for fact verification proceedings presented in October 2002.

- As DOCUMENT NO. 26, a copy of the Instrument from the Court of First Instance no. 72 of Madrid, dated 5th November 2002 and of the decision of 18th of the same month, accepting the application for proceedings and agreeing to send the respective letter rogatory.

- As DOCUMENT NO. 27, a copy of the Instrument dated 19th January 2003 from the Court of First Instance no. 72 of Madrid, refusing the opposition presented by LABORATORIOS BELMAC, S.A. and ordering the evidence of the proceedings carried out in Zaragoza to be delivered to ETHYPHARM, S.A.

- As DOCUMENT NO. 28, the original evidence issued by the Court of First Instance no. 72 of Madrid regarding the proceedings carried out in Zaragoza. The evidence was issued and delivered to this party on 15th February 2005, as may be seen on the last page with the signature of the Legal Secretary.

C) The technical verification of the infringement: expert's report provided on the documentation seized in Zaragoza

Once the evidence of the proceedings carried out in Zaragoza was received, ETHYPHARM, S.A. entrusted analysis of the seized documentation to the expert Mr. Rafael Sánchez, who had participated in the proceedings. The analysis of the documentation may be summarised in the following items:

(a) The expert commences his analysis by *paginating and numbering* the specific content of the documentation contained in the judicial evidence. He does so, logically, in APPENDIX I of his report, which constitutes the full photocopy of the evidence. The pagination is as follows:

- Folios 1 to 21: Handwritten instrument detailing the proceedings carried out in Zaragoza and a typed transcription of same;

- Folios 22 to 28: photocopies of the most relevant pages in the batches of Omeprazole micro pellets that were being manufactured at the time of the inspection;

- Folios 29 to 33: photocopy of the most relevant pages of the batches of Omeprazole micro pellets corresponding to the products manufactured by LABORATORIOS BELMAC, S.A., which had been acquired by ETHYPHARM, S.A. in October 2002: Omeprazole Cinfa, Omeprazole Leciva, Belmazol, Ulcometión, Omeprazole Davur, Omeprazole Acyfabrik and Omeprazole Farmygel;

- Folios 34 to 211: the complete manufacture dossiers on these same batches of Omeprazole;

- Folios 242 bis to 246: official communications from the Spanish Medicine Agency;

- Folios 247 to 248: photocopies of prospects and cardboard packaging of the Omeprazole found in the stores.

At the Court's request, the expert shall proceed to give this same pagination to the court evidence provided.

(b) The report also contains, as a general consideration, the description and explanation of the content and scope of invention patent no. ES 9301319. The expert confirms that this is a patent whose claims 1 to 6 refer to a pharmaceutical formulation or product. Mr. Rafael Sánchez informs that claim no. 1, the main claim, contains the essential characteristics of the patented formulation and that claims 2 to 6, which depend on the 1st, contain certain additional characteristics. His words in this regard are as follows:

" – The essential characteristics of the formulation patented in Ethypharm's Spanish patent no. 9301319, contained in claim 1, are as follows:

- *Stable formulation of omeprazole in form of granules*
- *Containing a neutral nucleus based on sugar and starch*
- *Plus an active layer based on a dilution of omeprazole in mannitol, in perceptibly equal quantities.*

- *The characteristics that are additional to the above essential characteristics are protected in claims 2 to 6, which depend on claim 1. The formulation may also contain:*

  - *10% weight of carboxymethylstarch in the active layer (claim 2)*
  - *5% of a tensioactive substance such as sodium laurylsulphate in the active layer (claim 3)*
  - *Mannitol on the surface of the active layer in the form of a complementary protective layer (claim 4)*
  - *A binding agent such as hydroxypropylmethylcellulose (claim 5)*
  - *A gastro-resistant coating such as Hydroxypropylmethylcellulose Phthalate and talc (claim 6)"*

(c) The initial object of the proceedings was to verify if LABORATORIOS BELMAC, S.A. was still, in December 2002, using the machinery provided by ETHYPHARM, S.A. to manufacture Omeprazole for orders other than those pending for the plaintiff. The Instrument that is attached to the evidence attests that the Judicial Committee entered the Room where the microgranules were prepared and the micro-pellets were manufactured and the machinery provided by ETHYPHARM, S.A. was functioning. At the request of this party, part of the dossiers corresponding to the micro pellets being manufactured were photocopied: batches Z 104, Z 112 and Z 093. The Manager of the Manufacturing Department at LABORATORIOS BELMAC, S.A. , Mr. Francisco Poderos, declared that he was not aware of who the "addressee" of the aforementioned batches was. After analysing the documentation, the expert has concluded that the batches being manufactured in December 2002 meet ETHYPHARM, S.A.'s patent. Mr. Rafael Sánchez examines this on a claim by claim basis:

" a) The formulation of the batches of OMEPRAZOL is included in claim 1 of ETHYPHARM, S.A.'s patent, for the following reasons:

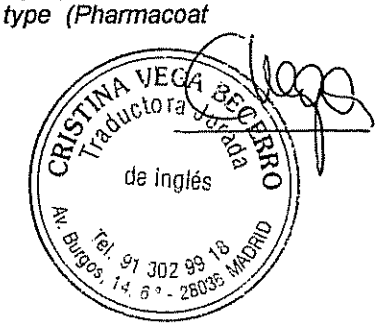
- *The product produced by LABORATORIOS BELMAC, S.A. is a formulation in the form of stable microgranules;*
- *The granules contains a neutral nucleus of sugar and starch (as may be seen in the final balance on page 24 of APPENDIX I);*
- *The granules contain, as well as the neutral nucleus, an active layer of a mixture of OMEPRAZOL and mannitol (same page); in this active layer, the quantities of OMEPRAZOL and mannitol are perceptibly equal (5 kilos of OMEPRAZOL; 5 kilos of mannitol: see, for example, page 23 of APPENDIX I);*

b) The formulation of the batches of OMEPRAZOL is also covered in claim 2 of ETHYPHARM, S.A.'s patent because it has an active layer containing carboxymethyl starch (Explotab). This appears on pages 23, 24, 26, 28, 29, 30, 31, 32 and 33.

c) The formulation of the batches of OMEPRAZOL is also covered in claim 3 of ETHYPHARM, S.A.'s patent because the active layer of OMEPRAZOL contains sodium laurylsulphate. This appears on pages 23, 24, 26, 28, 29, 30, 31, 32 and 33.

d) The formulation of the batches of OMEPRAZOL is also covered in claim 4 of ETHYPHARM, S.A.'s patent because the active layer of OMEPRAZOL contains a complementary protective coating composed of mannitol. This may be deduced from the final balances on pages 24, 26 and 28, where we can see a final quantity of mannitol that is higher than the ratio used in the formulation for the microgranules.

e) The formulation of the batches of OMEPRAZOL is also covered in claim 5 of ETHYPHARM, S.A.'s patent because in order to bind the active layer to the neutral nucleus, a binding agent in solution form is used (this is proven in the final balance on folio 24); this binding agent is of the Hydroxypropylmethylcellulose type (Pharmacoat or hypromellosa).



f) *The formulation of the batches of OMEPRAZOL is also covered in claim 4 of ETHYPHARM, S.A.'s patent because the formulation presents an outer gastro-protective coating composed of hydroxypropylmethylcellulose phthalate (HP 50) and talc. This appears on pages 24, 26 and 28".*

The files at LABORATORIOS BELMAC, S.A. are indicated as proof to find out the final destination of these batches being manufactured.

(d) The second objective of the proceedings was to determine the date of manufacture and formulation of the batches of Omeprazole from LABORATORIOS BELMAC, S.A. that ETHYPHARM had acquired in the market. The intention was to determine if they had been manufactured after 23rd March 2002, date on which the defendant had to cease using the technology belonging to this party. At the plaintiff's request, the manufacture dossiers of the aforementioned batches of Omeprazole Cinfa, Omeprazole Leciva, Belmazol, Ulcometión, Omeprazole Davur, Omeprazole Acyfabrik and Omeprazole Farmygel were photocopied at LABORATORIOS BELMAC, S.A.'s plant. Following analysis of these batches by the expert, it is confirmed that they were all manufactured by LABORATORIOS BELMAC, S.A. between 16th June 2002 and 2nd September 2002 and that the formulation referring to these batches is substantially equal to that of ETHYPHARM S.A.'s patent ES 9301319. To be specific, the expert addresses this issue as follows:

"- The product produced by LABORATORIOS BELMAC, S.A. is a formulation in the form of stable granules;

- *In the informative slip for these batches included on pages 73, 106, 153, 182 and 208, the full formula, which is substantially identical to that of ETHYPHARM, S.A.'s patent 9301319;*

- *The granules contain, as well as a neutral nucleus, an active layer of a mixture of OMEPRAZOL and mannitol (as may be seen on pages 29, 30, 31 and 32);*

- *The quantities of OMEPRAZOL and mannitol are perceptibly equal in this active layer (5 kilos in each one: pages 29, 30, 31 and 32);*

Moreover, the documentation indicates that claims 2 and 3 of the patent have also been infringed:

- *The formulation of the batches of OMEPRAZOL is also covered by claim 2 of ETHYPHARM, S.A.'s patent, because it includes an active layer containing carboxymethylstarch (Explotab). This appears on pages 29, 30, 31, 32 and 33 of APPENDIX I.*

- *The formulation of the batches of OMEPRAZOL is also covered by claim 3 of ETHYPHARM, S.A.'s patent, because the active layer of OMEPRAZOL contains sodium laurylsulphate. This appears on pages 29, 30, 31, 32 and 33 of APPENDIX I.*

If we had the final balance of these manufacture batches (pages 33 of 33 of the Manufacture Protocol), we could verify the presence of the components described in claims 4 to 6".

As for claims 4 and 6, the expert cannot make a statement because the full dossiers for batches Z 022, Z 030, Z 033 and Z 051 are missing.

(e) During the course of the proceedings, the judicial committee also entered the Encapsulation and Conditioning Rooms and the store at LABORATORIOS BELMAC, S.A. The Instrument and the seized documentation contain references to the batches of Omeprazole Davur that had been encapsulated and conditioned recently and the products Ulcometión, Omeprazole Davur, Omeprazole Acyfabrik, Belmazol 20 mg. and Omeprazole Farmygel that were in the store and of which the corresponding samples were seized. The expert was able to ascertain from the best-before date and by the formula described in these informative slips, that the Omeprazole had been manufactured after March 2002 and according to the formulation contained in patent no. ES 9301319.

(f) Finally, during the proceedings, LABORATORIOS BELMAC, S.A. was asked to provide a manufacture dossier for the Omeprazole that it had manufactured in the past under ETHYPHARM, S.A.'s patent and using its technology. There is a photocopy in the evidence of a batch manufactured in March 1998, the final balance of which, as the expert confirms, coincides in essence with ETHYPHARM, S.A.'s patent ES 9301319 and also with the manufacture dossier that was given to the expert and which constitutes APPENDIX III of the latter's report. It is interesting to highlight that Mr. Rafael Sánchez analyses in his report if the final balance that appears in these dossiers corresponds to the formulation in ETHYPHARM, S.A.'s patent and indicates in this regard:

"...the components used in the preparation are as follows:

(a) On the one hand, the essential components in ETHYPHARM's patent and described in claims 1 to 6: NHB (OMEPRAZOL); NEUTRALS (Sucrose and Starch); MANNITOL; EXPLOTAB (Sodium Carboxymethylstarch); SODIUM LAURYLSULPHATE;

FARMACOAT (Hydroxypropylmethylcellulose); HP 50 (Hydroxypropylmethylcellulose Phthalate).

b) On the other hand, this manufacture dossier also describes the following components: PVP K30 (Polyvinylpyrrolidone); MYVACET (Plastifying agent based on hydrogenated soya oil); ISOPROPYL ALCOHOL; ETHYL ALCOHOL and METHYLENE CHLORIDE (Dichloromethane). Of these components, the ISOPROPYL ALCOHOL, the ETHYL ALCOHOL and METHYLENE CHLORIDE disappear by evaporation during the process of manufacturing the formulation and are not included in its final composition. As for PVP, it is one of the binding components equivalent to FARMACOAT 606 (Hydroxypropylmethylcellulose). MYVACET is a plastifying agent normally used in the pharmaceutical industry".

(g) Lastly, we should add that the Court asked LABORATORIOS BELMAC, S.A. to show some additional documentation: the orders for Omeprazole received by this company after 24th March 2002; the sales invoices for various Omeprazole specialities after this same date; the delivery notes for Omeprazole manufactured for the firms ANTIBIÓTICOS FARMA, LABORATORIOS DAVUR, LABORATORIOS ACYFABRIK and LABORATORIOS FARMYGEL after 24th March 2002 and the manufacture and sale contracts and/or the licenses for the pharmaceutical authorisation.

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entered into after the said date by the defendant. The Instrument contains a statement from the Technical Director of this company saying that this documentation was to be found at LABORATORIOS BELMAC, S.A.'s corporate office in Madrid.

We attach as DOCUMENT NO. 29, the original decision issued by Mr. Rafael Sánchez Guillermo and the Appendices that belong to same. Please note the statement contained in this report:

" I hereby state that both as regards the prior inspections and verifications and as regards the decision issued, I have acted, and will act, with the greatest possible objectivity, taking into consideration both what may favour and what may harm either of the two parties and I am aware of the penal sanctions in which I could incur if I were to fail to perform by duties as expert".

SIXTH.- THE PERSISTENCE OF LABORATORIOS BELMAC, S.A. IN THE INFRINGEMENT AFTER THE FACT VERIFICATION PROCEEDINGS WERE CARRIED OUT IN DECEMBER 2002

(A) The capsules of Omeprazole manufactured by LABORATORIOS BELMAC, S.A. after 19th December 2002

In the period elapsed between the carrying out of the proceedings in December 2002 and the settlement of the incident by the Court of First Instance no. 72 of Madrid in February 2005, LABORATORIOS BELMAC, S.A. continued to manufacture Omeprazole according to the formulation in patent ES 9301319. This manufacture was presumably carried out using the machinery owned by ETHYPHARM, S.A. until 9th September 2003, on which date the machinery was removed. We shall refer in particular to the following products:

- A batch of Belmazol 20mg. Capsules of Omeprazole (S1), whose best-before date is January 2005, meaning that it would have been manufactured in January 2003.
- A batch of Davur 20mg. (V 008), whose best-before date is January 2006, meaning that it would have been manufactured in January 2004.
- A batch of Belmazol 20mg. (V 003), whose best-before date is January 2006, meaning that it would have been manufactured in January 2004.
- A batch of Omeprazole Farmygel (V 034), whose best-before date is September 2006.

We hereby attach, as DOCUMENT NO. 30, the photocopies of the packaging and informative slips for these products. The originals were sent, as shall be explained now, for technical analysis. They contain a reference to LABORATORIOS BELMAC, S.A. as manufacturer. For the purposes of evidence, we indicate not only the manufacture dossiers contained in LABORATORIOS BELMAC, S.A.'s files, but also the defendant's own library of samples of the capsules corresponding to these batches.

(B) The inexistence of any change in the formulation: the absence of the new health registrations obtained by LABORATORIOS BELMAC, S.A. for marketing Omeprazole

The fact that LABORATORIOS BELMAC, S.A. maintained the same Omeprazole manufacturing formula as provided by ETHYPHARM, S.A. at the time is clearly demonstrated by the lack of new health registrations obtained for this purpose by the defendant. In this regard, we hereby attach the following:

- As DOCUMENT NO. 31, the paper print-out of the pages of the website www.belmac.com regarding the Belmazol manufactured by the defendant. They contains the two technical files authorised by the Spanish Medicine Agency to this company. These files are as follows: Belmazol 20 mg. (First authorisation in January 1993, revised in February 2001) and Belmazol 10 mg. (June/ September 2003). You will remember that the first technical file was the one obtained during the period of relations between ETHYPHARM, S.A. and LABORATORIOS BELMAC, S.A.. Well, the formulation of the latter technical file obtained by LABORATORIOS BELMAC, S.A. for Omeprazole is identical to the former. The only perceptible change is in the coating for the gelatine capsule (the addition of iron oxide), which does not affect the actual formulation of the product.

- As DOCUMENT NO. 32, we provide the full list of pharmaceutical specialities granted by the Spanish Medicine Agency and which may be consulted on the webpage of this public Body. It does not include any pharmaceutical speciality granted to LABORATORIOS BELMAC, S.A. after June 2003.

(C) The irrelevance of ulterior patents obtained by LABORATORIOS BELMAC, S.A. for Omeprazole

This party has been informed that LABORATORIOS BELMAC, S.A. has obtained registration for an invention patent for an *"improved process for obtaining stable and gastro-resistant pellets of Omeprazole, pellets thus obtained and applications"*. This patent was applied for on 6th April 2001 and was recently granted by the Spanish Patents and Trademarks Office. Its relevance in the issue being debated in this proceeding is null, apart from the legal questions that will be exposed later on, if one realises the analysis carried out by the expert Mr. Rafael Sánchez in his report. According to the expert, the patent held by LABORATORIOS BELMAC, S.A. *would be included in ETHYPHARM's patent no. 9301319 for the following reasons*:

"a) The patent refers to procedures for obtaining stable pellets of Omeprazole whose formulation is substantially identical to the one protected in claims 1 to 6 of ETHYPHARM's patent. In particular, the formulation includes the following essential components:

- *Neutral agents (Sucrose and starch)*
- *Omeprazole*
- *Mannitol (concentration substantially identical to that of Omeprazole)*
- *Carboxymethylstarch*
- *Sodium Laurylsulphate*

b) The only components present in the formulation of patent ES 2192929 in comparison to ETHYPHARM's patent would be the following:

- *Polyvinylpyrrolidone (which is a binding agent equivalent to the Pharmacoat or hydroxypropylmethylcellulose claimed in ETHYPHARM's patent)*
- *Isopropyl Alcohol (which disappears in the manufacture process and therefore does not make up the final composition of the formulation)*

c) These components were already being used prior to the date of application for BELMAC's patent, as is shown in the dossier provided as APPENDIX III".

We hereby attach as DOCUMENT NO. 33, the text of patent number 2192929 held by LABORATORIOS BELMAC, S.A., which may be obtained from the database of the Spanish Patents and Trademarks Office.

D) The additional technical verification provided for the current Omeprazole manufactured by LABORATORIOS BELMAC, S.A.

Although the evidence and indications point to the fact that LABORATORIOS BELMAC, S.A. continued to manufacture Omeprazole according to the formulation claimed in patent number ES 9301319 and using the technology provided by ETHYPHARM, S.A., my client wished to subject the most recent capsules of Omeprazole on the market to a technical analysis.

We provide in this regard and as DOCUMENTS NOS. 34, 35 and 26, the reports issued by Professor Robert Rosset in April of this year, analysing respectively one tablet of Omeprazole from the batches purchased by ETHYPHARM, S.A. and mentioned previously in this writ. The final result or conclusion to all the tests, after analysing the Omeprazole microgranules using the infra-red spectrometry technique is unequivocal: the percentage of Omeprazole and mannitol used substantially coincides with the quantities claimed in patent no. ES 9301319.

Medicine	Batch	Best-before date	% Omeprazole	% Mannitol
BELMAZOL 20 mg	S1	01.2005	52.1	47.9
DAVUR 20 mg	V008	01.2006	52	48
BELMAZOL 20 mg	V003	12.2006	44.4	55.6

SEVENTH.- THE LOSSES AND DAMAGES DERIVED FROM VIOLATION OF ETHYPHARM, S.A.'s PATENT AND FROM THE UNLOYAL BEHAVIOUR OF LABORATORIOS BELMAC, S.A.

(A) The mark-up that the sale of the Omeprazole manufactured by LABORATORIOS BELMAC, S.A. represented for ETHYPHARM

The relations between ETHYPHARM, S.A. and LABORATORIOS BELMAC, S.A. for Omeprazole were based on the setting of a price for the sale of the product manufactured by the defendant. This price varied depending on whether the product was Omeprazole corresponding to an order from ETHYPHARM, S.A., Omeprazole manufactured for internal consumption by LABORATORIOS BELMAC, S.A. (its own products or orders from its customers) and Omeprazole destined for export. The mark-up obviously varied over the years This party has calculated the corresponding average as 250 Euros per kilo of Omeprazole converted to microgranules. We can now confirm the presentation of an accounting report, which was not available at the time the suit was filed, confirming this data.

B) Quantification of the damages from the manufacture and sale of Omeprazole from 23rd March 2002 onwards

The compensation for losses and damages should be calculated on the basis of the units sold and the kilos of Omeprazole manufactured by LABORATORIOS BELMAC, S.A. after 23rd March 2002 and until the date on which the sentence to this suit is issued. For the purposes of evidence, this party hereby states the following:

- First of all, we provide, as DOCUMENTS NOS. 37 and 28, the certificates issued by the specialist company IMS HEALTH, S.A. on the units sold and the total turnover of the Omeprazole specialities in the years 2002, 2003 and 2004.

- We indicate LABORATORIOS BELMAC, S.A.'s files because of the obligation that they be revealed. In the ADDITIONAL PLEADING, LABORATORIOS BELMAC, S.A. is specifically requested to provide the Court with a certificate, approved by its auditor, containing the following information: (i) Omeprazole pharmaceutical specialities manufactured by LABORATORIOS BELMAC, S.A. for its own products or for third parties and destined for export after 23rd March 2002 (ii) kilos of Omeprazole manufactured since 23rd March 2002 for the aforementioned pharmaceutical specialities.

- We propose as evidence, also in the ADDITIONAL PLEADING, that the Court appoint an expert accountant so that by analysing the invoices, official books, accounting documents and any other necessary document owned by the company ETHYPHARM, S.A. or by the defendant LABORATORIOS BELMAC, S.A., it may be possible to certify: (i) the average price that LABORATORIOS BELMAC, S.A. paid to ETHYPHARM, S.A. for the manufacture and sale of Omeprazole pharmaceutical specialities (ii) the price that LABORATORIOS BELMAC, S.A. should have paid to ETHYPHARM, S.A. for the manufacture and sale by LABORATORIOS BELMAC, S.A. of Omeprazole specialities after 23rd March 2002.

GROUNDS OF LAW

-I-

BASES OF SUIT

1. Jurisdiction and nature of suit

Article 22.1 of the Judiciary Act, as regards the competence of the Spanish courts to instruct this suit, regarding article 36 of the Civil Prosecution Act 1/2000 of 7th January (hereinafter, Act 1/2000).

Article 125.1 of the Patents Act, in the text given to same by the Final Fifth provision of Act 1/2000, according to which:

"Civil suits arising within the scope of this Act shall be settled in the trial that corresponds according to the Civil Prosecution Act".

Article 249.1.4º of the Civil Prosecution Act 1/2000, regarding the kind of suit applicable and within the scope of the Ordinary Suit, to whose substantiationthe following are assigned:

" 4.º Suits on the matter of unfair competition, industrial property, intellectual property and advertising, as long as they are not exclusively over quantity claims, in which case they shall be subject to the procedure corresponding depending on the amount being claimed".

2.Objective Competence

Item 2 of article 86 ter of the Civil Prosecution Act (according to the modification introduced by Organic Law 8/2003 of 9th July on Competition reform), regarding the competence of the Mercantile Courts on the matter of industrial property, by which:

"2. The mercantile courts shall also examine any issues regarding the following, when they fall under the competence of the civil jurisdictional order:

a) *Suits in which action is taken regarding unfair competition, industrial property, intellectual property and advertising, as well as all issues that are promoted within this jurisdictional order under the auspices of the regulations governing mercantile companies and co-operatives".*

3. Territorial competence

Number 13 in item 1 of article 52 of the Civil Prosecution Act, by which:

"On the matter of patents and trademarks, the Court indicated by the special legislation on this matter shall be competent".

Item 2 of article 125 of the Patents act, by which:

" The Judge of 1st Instance of the city where the Higher Court of Justice of the Autonomous Community corresponding to the defendant's domicile shall be competent".

4. Legitimation

The plaintiff company, ETHYPHARM, S.A. is actively legitimated to exercise this suit, as the holder of the Patent that is the object of the said suit, in conformity with the terms of article 62 of the Patents Act of 20th March 1986, as regards article 10 of Act 1/2000.

The defendant is passively legitimated to bear this suit as the company in charge of manufacturing and selling the products that infringe upon the exclusive rights derived from the aforementioned industrial property registration.

5. Postulation

Representation by a Solicitor and assistance by an Attorney are mandatory, as it is an Ordinary Suit that is not exempt from Postulation, according to the terms of articles 23 and 31 of Act 1/2000.

6. Probatory Activity

Article 328 of act 1/2000, regarding the obligation of the parties to show documentation, by which:

" 1.Each of the parties may request that the other parties show documents not in the former's possession and referring to the object of the suit or to the efficiency of the means of evidence.

2. Requests to show documents must be accompanied by a simple copy of the document and, if it does not exist or is not available, the content of same shall be indicated in the most exact terms possible."

-II -

RIGHTS DERVIED FROM THE PLAINTIFF'S OWNERSHIP OF THE PATENT ES 9301319 AND INFRINGEMENT OF SAME IN THE MANUFACTURE AND SALE OF OMEPRAZOL BY THE DEFENDANT

1.- Notion and regulation for patent

The Spanish Patents Act of 20th March 1986 acknowledges in its Preamble that the legislation on this matter *"has a decisive influence on how the economy is organised, as it constitutes an essential element for promoting technological innovation"*, also adding the following:

" A patents act that efficiently protects the results of our research constitutes an element that is necessary within the Spanish policy to promote research and technological development".

From the general regime applicable to patents in our country, we should highlight the following as the departure point:

(a) That according to the terms of article 4 of the Act, *new inventions that imply inventive activity and are liable for industrial application* may be patented.

(b) That according to the terms of article 49, the patent *has a duration of 20 years that may not be further extended, counting from the date on which the application is presented and it enters into force on the date on which the notification of its being granted has been published.*

(c) That patents can traditionally include claims referring to the product and claims referring to the process for manufacturing the product. In the pharmaceutical sector, patents for *products* are feasible since 7th October 1992, by virtue of the terms of the First Transitory Provision, by which:

"1. Inventions of chemical and pharmaceutical products prior to 7th October 1992 shall not be eligible for patents.

2. Until this date, none of the articles contained in this Act and referring to the patentability of inventions of chemical or pharmaceutical products and none of the other precepts that are unquestionably related to the patentability of same shall have any effect.

3. The terms of the above provisions does not affect inventions of procedures or apparatus for obtaining chemical or pharmaceutical products, nor to procedures for using chemical products, all of which may be patented according to the regulations of this Act from the moment it enters into force".

2.- Scope of the right to exclusiveness in the case of *product* patents

The legal regime applicable to the invention patent, as is the case with any modality of intellectual property, is based on *ius prohibendi* or *ius excludendi alios*. The registered holder of a patent enjoys a right to exclusiveness that allows it to take action against any undertaking intending to exploit the claimed object without its consent. Article 50 of the Patents Act specifies this regime of exclusiveness or this legal monopoly in the following terms:

" The patent confers on its holder the right to prevent any third party without the former's consent, from:

a) Manufacturing, offering, introducing in the market or using a project that is the object of the patent or importing or possessing same for one of the aforementioned purposes.

b) Using a procedure that is the object of the patent or offering to perform such use, when the third party knows or the circumstances clearly indicate that use of the procedure is prohibited without the consent of the patent holder.

c) Offering, introducing in the market or using the product directly obtained by the procedure that is the object of the patent or importing or possessing the aforementioned product for one of the aforementioned purposes."

Any action to offer or use the object without the consent of the holder shall constitute an infringement of the exclusiveness. Obviously, in the case of the patent for a pharmaceutical *product*, the protection is extended to the formulation of the product *no matter which*

manufacture procedure is used. If the result of the procedure still results in the same formulation, the infringement subsists.

3.- Infringement of a patent *by equivalence*

When considering if the infringing product constitutes an infringement of the patent, any changes that have been introduced but which have not led to any change in the result are entirely lacking in importance. Our legal system also contemplates the infringement of a patent by *equivalence*.

In fact, the doctrine of equivalence is understood to mean that which postulates a wide interpretation of the content of the patented invention in order to avoid unconsented use by third parties of technical solutions which, although not included in literal terms in the claims for the patent, present insubstantial variations on the elements contained in same. The doctrine departs from the need to protect the patent beyond what its claims express *ad pedem literae*. By virtue of this doctrine, the patent is understood to protect not only the elements that are explicitly mentioned in the claims, but also all other elements or forms of embodiment that despite being alternatives, lead to equivalent results.

This doctrine of equivalence is currently supported by an unquestionable legal structure. Among other regulatory provisions, we beg to quote the following:

- Article 60.1 of the Patents Act, according to which,

  " The extension of the protection conferred by the patent or by the patent application is determined by the content of the claims. However, the description and the drawings serve to interpret the claims".

- Article 69.1 of the Agreement of 5th October 1973 on the granting of European patents, which entered into force in Spain as from 1st October 1986, by which:

  "The scope of the protection afforded by the European patent or European patent application shall be determined by the content of the claims. However, the description and the drawings shall serve to interpret the claims".

- The protocol that interprets the Agreement on European patents, which forms an integral part of same, containing the following statement:

"Article 69 should not be interpreted in the sense that the scope of the protection afforded by the European patent should be understood according to the strict and literal meaning of the text of the claims and that the description and the drawings serve solely to dissipate ambiguities that may be contained in the claims. Neither should it be interpreted in the sense that the claims serve only as a guideline and that the protection is extended also to what, in the opinion of an official person that has examined the description and the drawings, the holder of the patent wished to protect. Article 69 should rather be interpreted in the sense that defines, among other things, a position that ensures at the same time fair protection for the applicant and a reasonable degree of certainty to third parties."

The doctrine of equivalence is currently a consolidated doctrine in Spanish case law. The courts have laid down that when the changes do not affect the global notion of the invention or the essential principle that inspires the latter, representing merely the replacement of some elements by others, the infringement still stands.

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The 1st Courtroom of the Supreme Court seemed to come close to the doctrine of the " general inventive concept" in its sentence of 13th December 1989, declaring that:

"Nobody can take advantage of another's idea in order to present it as its own under the pretext of having introduced small and insubstantial modifications in the layout or use".

The 15th Section of the Provincial Court of Barcelona first referred to the doctrine of equivalence in its sentence of 15th March 2000 (JUR 2000/ 182856), indicating in this regard:

" FIFTH. The plaintiff, both in the explanations requested from the experts and in the last statements made in the second instance, centres the question on what is considered to be the equivalence between the component for guiding the coils, as is claimed in intervention patent number 541.248 held by SUPERBA and the component for guiding the coils foreseen in the HB1 machine by MOTOCONO, in its three versions.

It refers basically to what constitutes an infringement by equivalence and quotes, among others, the Sentence from the Contentious-Administrative Courtroom of the Supreme Court of 5th December 1967, in the sense that it is not possible to avoid the course of the principle of equivalence by which, in the protection of any registered invention, it is understood to include all the variations in terms of form, material, size, layout of elements or any replacement of these elements by others, if this does not alter the fundamental principle of the invention described, claimed and protected by the patent or the utility model already in existence in the registration.

The plaintiff states that the equivalence between the coil guiding components is not dismissed by the fact that in the case of SUPERBA, the guiding component is a single part (sable) and in the case of MOTOCONO, two parts (sable or collar + application guide) because both solutions fulfil the same function, operate in the same manner and obtain the same result."

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However, it is in the sentence issued by the Provincial Court of Barcelona (15th Section) of 18th September 2000 (AC 2054) where the principle of equivalence was finally established. The terms in which the sentence is issued are as follows:

> *" As a rule, it may be said that, according to the terms of article 26 of the Patents Act, the claims define the object for which protection is sought, which means that, according to 60.1, "extension of the protection conferred by the patent or by the patent application is determined by the content of the claims".*

However, efficient protection of the right of the inventors does not tolerate that the monopoly be overcome by introducing in the invention any irrelevant modification that destroys the absolute equality between the invention and the new procedure, giving rise to the doctrine of "equivalence", whereas the latter is understood to mean "variations in terms of form, material, size, layout of elements or any replacement of these elements by others, if this does not alter the fundamental principle of the invention described, claimed and protected by the patent or the utility model" (sentence from 3rd Courtroom of 10th June 1968 [RJ 1968/ 3155]), or "when the means perform the same function to achieve an identical result despite the fact that the forms of embodiment may be different", fulfilling the same function " when they proceed from the same basic idea, i.e. when they apply the same principle in the same manner", whereas the result is identical when "it is of the same nature and the same quality" (decision of 15th June 1994 in appeal no. T 697/1992 of the European Patents Office).

In our sentences of 3rd January (AC 2000/685) and 10th February this year – Bayer vs. Impex (case of ciprofloxacin), and Pfizer vs. Cehmo Ibérica (case of fluconazol)-, in cases that present certain similarities, we adopted the position maintained by the Supreme Court in its sentences of 13th October 1975 (RJ 1975/3420) and 13th October 1982 (RJ 1982/5761), whereas the concept of chemical or pharmaceutical procedure is understood to be delimited by the combination of three elements: the basic departing substance; the procedure followed on this substance; and the end product or result."

This case law has been ratified in the recent sentence of the 15th Section of the Provincial Court of Barcelona on 14th October 2002 (JUR 2004/14120), according to which:

" In order to examine the infringement exercised by the reconvention method (and symmetrically, the jactitation suit intended by the defendant, which was assessed in the sentence of 1st Instance), it is not irrelevant to point out that the theory of the claims that determines efficient protection of the rights of the inventors (and which is applicable to the utility models by the reference made in article 154), does not lose its validity because of the simple introduction of any irrelevant modification that destroys the absolute identicality between the controverted model with which it was registered by the plaintiff, which constitutes the theory of equivalence (to which the plaintiff referred in the minutes of the hearing and which was mentioned in our sentence of 14th January 1999 – Roll 131/97-), whereas these are understood to mean "variations in terms of form, material, size, layout of elements or any replacement of these elements by others, if this does not alter the fundamental principle of the invention

described, claimed and protected by the patent or the utility model", or when "the means perform the same function to achieve an identical result despite the fact that the forms of embodiment may be different", fulfilling the same function " when they proceed from the same basic idea, i.e. when they apply the same principle in the same manner", whereas the result is identical when "it is of the same nature and the same quality" (decision of 15th June 1994 in appeal no. T 697/1992 of the Spanish Patents Office).

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SEVENTH.- Recognition of the apparatus provided for the initiatives marketed by SOLAC, S.A., by the names "Professional Epil", "Super Epil" and "Hidratant Epil" indicates the existence of a series of circumstances that are common to those described by model no. 8900037 contained in the aforementioned report issued by the SPTMO-f. 1.469 -, i.e.: a) they are formed by a shell that is formed by two half-shells; b) there is a sleeve inside the shell; c) the shells are divided in two parts on the longitudinal plane; d) there are resistances attached to the side and outer surface of the sleeve; e) the wax-containing deposits present a configuration to that of the shell that houses them; f) the resistances, in this particular device, are governed by a fixed thermostat in order to maintain an ideal temperature for applying the wax; g) the shell, the sleeve and the electrical resistances are fitted together so as to form a small body, which in combination with a complementary container deposit allows to perform a hair removal process in which the wax remains hot for the whole process of hair removal; h) the wax applying device is portable.

Without prejudice to the differences in what was called the philosophy of use of the utensils being compared (as was noted by the expert that intervened in proceeding 866/96 followed before Court no. 43 in Barcelona), the remaining differences between both (the fact that the plaintiff's device was formed by a single part and the defendant's by two, the fact of one having a handle and a switch and not the other and the fact that the device protected by utility model 8900037 had constant connection to the electrical network – which may be eliminated by means of the function the device is called to perform without detriment to same – and not the one marketed by the defendant), may be considered to be non-transcendent, as the purpose and the mode of operation of the instruments examined are the same. Thus concludes the repeated report from the SPTMO – f. 1.472 – and this is the conclusion to which the Courtroom arrives, which means that the appealed sentence is repealed and the reconvention suit filed by the plaintiffs is accepted, with the consequences of cessation, seizure and destruction of all of the products that infringe upon the protected right and of the frames used by ELECTRODOMÉSTICOS SOLAC, S.A. to manufacture same".

4.- Lack of any virtue in possible allegation to the contrary based on LABORATORIO BELMAC, S.A.'s patent no. 2192929: articles 55 and 56 may be invoked for this purpose

The fact that LABORATORIOS BELMAC, S.A. is in possession of an invention patent for the manufacture of Omeprazole – regardless of whether it may be being used or not – does not exonerate the defendant of its liability for infringement of patent no. ES 9301319.

(a) Patent no. 2192929 was applied for by the defendant at a later date after ETHYPHARM's patent and regarding a technology that had been provided to the former by the plaintiff and which the former had been applying with the machinery owned by the plaintiff. In this regard, we should remember that the rights must be exercised on a bona fide basis and that the system does not support either the abuse of law or actions performed outside the law. Articles 6.4 and 7 of the Civil Code constitute an elementary departure point in this regard.

(b) The Patents Act expressly regulates this type of cases in which the defendant intends to support its action on a registration that is more recent than the one on which the suit for violation filed against the defendant is based. We refer here to article 55 of the Act, according to which:

"The holder of a patent may not invoke the latter to defend itself against suits directed against itself for reasons of violation of other patents whose priority date is prior to that of its own"

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The disappearance of these *"cover-up patents"*, as they are known, constitutes one of the most highly acclaimed achievements in the now not so recent reform of patents legislation in our country. The effect of this elimination is very clear and was explicitly included in the sentence issued by the First Courtroom of the Supreme Court on 19th October 1993 (RJ 7742):

" We must bear in mind that as the minutes contain a suit for reasons of infringement of patent rights filed in the name of Mr. José B.P., the nucleus of the question is, as the appealed sentence indicates, to determine if these machines manufactured by the defendant are equal to those patented by the plaintiff; which means that, as Art. 55 LP states, the holder of a patent may not invoke the latter to defend itself against suits directed against itself for reasons of violation of other patents whose priority date is prior to that of its own; whereas the priority, in this case, favours the appealed plaintiff, i.e. it is not a question of carrying out a comparative examination between the claims of each patent, but rather of determining if the machines that are said to have been built in infringement of the plaintiff's patent right are substantially identical to the machines protected by this patent, or on the contrary, if they introduce innovations that constitute inventive activity [...]"

(c) Even if we are to ignore these last two considerations, neither could the patent play any role in the controversy inasmuch as it would be a patent that would be *"dependant"* on ETHYPHARM,S.A.'s patent. In other words, its object could never be used *for* the manufacture of an Omeprazole whose formulation is protected by a previous patent. The *dependence* between patents is explicitly regulated in article 56 of the Act, according to which:

> *" The fact that the invention that is the object of a patent cannot be exploited without using the invention protected by a previous patent belonging to a different holder shall not be an obstacle to the validity of the patent. In this case, neither will the holder of the previous patent be allowed to exploit the ulterior patent during the term of validity of the latter without the consent of its holder and neither will the holder of the ulterior patent be allowed to exploit either of the two patents during the term of validity of the previous patent, unless it obtains the consent of the holder of same or has been given a mandatory license".*
>
> In other words, without detriment to the fact that the defendant may make use of the processes in its patent for other purposes, the use of same to produce Omeprazole according to the formulation patented by ETHYPHARM, S.A. would require the explicit consent of the latter, inasmuch as the object of this patent could not be exploited without using at the same time the invention protected in patent no. ES 9301319.

-III-

ACTIONS TO WHICH THE HOLDER OF THE PATENT RIGHTS IS ENTITLED

1.- General regime

The Patents Act lays down in favour of the holder of an Industrial Property right a system of actions structured around three basic premises: the cessation of the infringing activity (suspension of the manufacture and sale of the infringing product), the removal of the property and instruments used in the infringement (removal from the market and destruction of illegal specimens) and the restitution for the losses and damages incurred (financial compensation).

Thus, article 62 of the act lays down that the holder of a patent and also the holder of a utility model by virtue of the references contained in articles 152 and 154,

"May exercise before the bodies of the ordinary Jurisdiction, the corresponding actions, regardless of their class and nature, against those who infringe upon its right and request the necessary measures to safeguard the latter".

The specific content of the actions of cessation and removal are laid down in article 63, by which:

" The holder whose patent right is infringed may, in particular, request the following:

a) Cessation of the acts that infringe upon its right.

b) Compensation for the losses and damages suffered.

c) Seizure of the objects produced or imported in infringement of its right and of the means exclusively destined to such production or to the performance of the patented procedure.

d) Assignment in ownership of the objects or means seized by virtue of the terms of the previous provision where possible, in which case the value of the affected goods will be included in the amount of the compensation for losses and damages. If the value mentioned exceeds the amount of the compensation granted, the holder of the patent should compensate the other party for the excess.

e) The adoption of the necessary measures to prevent the infringement of the patent to continue and, in particular, the transformation of the objects or means that are seized by virtue of the terms of item c), or destruction of same when such destruction is indispensable in order to prevent infringement of the patent.

f) Publication of the sentence against the party infringing upon the patent, at the sentenced party's cost, in the form of announcements and notifications to interested parties. This measures shall only be applicable when the sentence expressly deems this to be necessary".

2.- Intention to restitution

The Act takes special care in regulating the compensatory action. For article 64,

"1. Any person that without the consent of the holder of the patent, manufactures, imports objects protected by same or uses the patented procedure, shall in all circumstances be obliged to take liability for the losses and damages caused"

In order to determine the losses and damages, the Act provides two accumulative criteria and three optional parameters regarding the second of these. In conformity with the terms of article 66,

" 1. The compensation for losses and damages due to the holder of the patent shall include not only the value of the loss incurred, but also the value of the profit that the holder has failed to obtain as a result of the infringement of its right.

2. The profit not earned shall be determined, at the affected party's choice, according to one of the following criteria:

a) According to the profits that the holder might foreseeably have obtained by exploiting the patented invention if the competence of the infringing party had not existed.
b) According to the profits that the latter has obtained from exploiting the patented invention.

c) *According to the price that the infringing party would have had to pay to the holder of the patent for the granting of a license that would have allowed it to carry out its exploitation within the law.*

In determining this amount, the following factors, in particular, shall be taken into consideration: the economic importance of the patented invention, the duration of the patent when the infringement commenced and the number and types of licenses currently granted.

3. *When the Judge decides that the holder should not comply with the obligation to exploit the patent established in article 83 of this Act, the unearned profit shall be determined in accordance with the terms of letter c) in the previous item."*

As for the period of time of the infringing activity subject to compensation, article 71.2 of the Patents Act states the following:

" 2. Compensation for losses and damages may only be claimed for events occurring in the five years previous to the date on which the corresponding action is exercised".

3.- Proof of damages

For the purposes of proof regarding the intention of restitution, we expressly quote article 65 of the Patents Act, according to which,

" In order to determine the amount of the losses and damages suffered by the unauthorised exploitation of the invention, the holder of the patent may request that the liable party show documents to serve this purpose".

As for the case law interpretation of damages in the sphere of industrial property, we beg to quote Sentence no. 1217/2004 issued by the First Courtroom of the Supreme Court on 23rd December 2004, as it goes over the case law existing on this matter and concludes in the following terms:

"...and therefore, it is also convenient to go over what was declared by this Courtroom in some of its sentences, regarding the imperious requirement to prove the losses and damages in the declaration process (STS 20-2-01 in appeal no. 361/96) or on the lack of consolidation of the doctrine regarding damages "in re ipsa" on these matters (SSTS 29-903 in appeal no. 3908/97 and 3-3-04 in appeal no. 889/98), by what was decided by others that consider losses and damages to be a necessary consequence of the infringement (SSTS 23-2-98 in appeal no. 3359/94, 17-11-99 in appeal 790/95, 7-12-01 in appeal no. 2483/96 and 19-6-03 in appeal no. 328/97), because there will be very few infringements that do not report any benefit to the infringing party, or do not cause any loss to the plaintiff interested in cessation of the illegal situation, if we consider the economic interest that presides these spheres, generally linked to business activities, and even the possibility of moral damages admitted by this Courtroom in its sentence of 18th February 1999, when it settled an appeal to the highest instance on the subject of trademarks where the plaintiff was a natural person".

-IV-

IMPOSITION OF COSTS

The costs are imposed on the defendant according to the terms of article 394 of Act 1/2000, according to which,

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" In declaratory suits, the costs of the First Instance shall be imposed on the party whose intentions have been refused, unless the Court determines and reasons that there were serious doubts of fact or law in the case".

In the event of submission, we expressly quote the second paragraph of article 394, according to which,

"Bad faith shall be understood to prevail in any case if before the suit is presented, the defendant has been given a reliable and justified request for payment, or if it has been sent a settlement demand".

By virtue of which,

I HEREBY BEG OF THE COURT, considering this writ to have been submitted along with the documents and copies that accompany same and an ordinary suit to have been filed on behalf of the company ETHYPHARM, S.A. against the company LABORATORIOS BELMAC, S.A., to agree to admit this suit and after the opportune legal proceedings, to issue a Sentence:

1 DECLARING

That the offering, manufacture and/or marketing by the defendant company, LABORATORIOS BELMAC, S.A. of the Omeprazole specialities that are the object of this suit, constitutes a violation of the rights derived from claims 1 to 6 of Patent no. 9301319.

2 ORDERING THE DEFENDANT

a) To attend and hear the above statements.

b) To immediately cease from offering, manufacturing, selling and/or exporting the Omeprazole specialities referred to in this suit.

c) To abstain from then on from any activity of offering, manufacturing, marketing, selling and/or exporting the pharmaceutical Omeprazole specialities included in the scope of the claims in patent no. ES 9301319.

d) To remove from the market and destroy any catalogues, leaflets or documents referring to the aforementioned pharmaceutical Omeprazole specialities, including the reference on its website in Internet.

e) To compensate the plaintiff ETHYPHARM, S.A. for the losses and damages caused, as a result of the price that LABORATORIOS BELMAC, S.A. would have had to pay to ETHYPHARN, S.A. for the manufacture and sale of the Omeprazole pharmaceutical specialities after 23rd March 2002 and until the sentence is executed.

All of the foregoing with the express imposition of costs on the defendant.

FIRST ADDITIONAL PLEADING. Presentation of the suit within the term established in article 131.2 of the Patents Act.

We hereby declare for the record that this suit writ is filed within the term of two months established in article 131.2 of the Patents Act of 20th March 1986 counting from the fact verification Proceedings. Obviously, the *dies a quo* for calculating this term is none other than that of the notification of the Instrument from the Court of First Instance no. 72 in Madrid which failed to admit the opposition on 10th February 2005 last. This Instrument is the one that allowed this party to be delivered the necessary judicial evidence to prepare the suit..

I HEREBY BEG THE COURT to consider the above statement for the opportune purposes.

SECOND ADDITIONAL PLEADING. Requirement for defendant to show documentation.

That this party is interested, in accordance with the terms of article 328 of the Civil Prosecution Act, that when LABORATORIOS BELMAC, S.A. be summoned to answer the suit, the defendant be requested to provide the following documentation along with its answer:

(a) A copy of the pages in the Manufacture Protocols for Batches Z 104, Z 112 and Z 093 of Omeprazole that state the pharmaceutical speciality or destination to which they are referred.

(b) A copy of pages 33 of 33 of the Manufacture Protocol for Batches Z 022 Z 030, Z 033, Z 029 and Z 051 of Omeprazole that state the final balance of the batches.

(c) A copy of the manufacture and sale contracts entered into by LABORATORIOS BELMAC, S.A. after 24th March 2002 regarding the pharmaceutical speciality Omeprazole.

(d) A copy of the licenses or leases entered into with third parties by LABORATORIOS BELMAC, S.A. regarding the pharmaceutical authorisations obtained for the speciality Omeprazole.

(e) A copy of the pages in the Manufacture Protocol for the batches of Belmazol 20 mg. Omeprazole capsules (S1); Davur 20 mg (V008); Belmazol 20 mg. (V003) and Omeprazole Farmygel (V 034), that state the formulation and the final balance.

(f) A complete list of the Omeprazole pharmaceutical specialities manufactured by LABORATORIOS BELMAC, S.A. for itself or for third parties and destined for exportation after 23rd March 2002.

(g) The total volume, certified by auditor, of kilos of Omeprazole manufactured since 23rd March 2002 for the aforementioned pharmaceutical specialities.

I HEREBY BEG THE COURT that in accordance with the above pleading, request in the letter rogatory that the defendant provide the above documentation along with its answer to the suit.

ADDITIONAL THIRD PLEADNING: Judicial appointment of an expert accountant.

- In accordance with the terms of article 339.2 of the standing Civil Prosecution Act, this party is interested in the judicial appointment of an expert accountant in order that so that by analysing the invoices, official books, accounting documents and any other necessary document owned by the company ETHYPHARM, S.A. or by the defendant LABORATORIOS BELMAC, S.A., it may be possible to certify: (i) the average price that LABORATORIOS BELMAC, S.A. paid to ETHYPHARM, S.A. for the manufacture and sale of Omeprazole pharmaceutical specialities (ii) the price that LABORATORIOS BELMAC, S.A. should have paid to ETHYPHARM, S.A. for the manufacture and sale by LABORATORIOS BELMAC, S.A. of Omeprazole specialities after 23rd March 2002.

I HEREBY BEG THE COURT to consider the above pleading for the opportune purposes.

FOURTH ADDITIONAL PLEADING. Reservation made for the judicial appointment of a technical expert.

In accordance with the terms of article 339.2 of the standing Civil Prosecution Act, this party wishes, for the case of a challenge by the defendant of the expert's report provided or a discrepancy regarding its content and scope, that the Court should proceed to the judicial

appointment of an expert, whereas we hereby propose the Patents Centre in the University of Barcelona. Professor. Pascual Segura, the Director of this centre, enjoys great prestige and is highly specialised in the issue of decisions regarding pharmaceutical patents. Articulation of the evidence and specification of what should be examined shall be carried out depending on the answer to the suit, in the prior Hearing proceeding or at the Court's request. The address of this Centre is as follows:

Parc Científic de Barcelona
Baldiri Reixac, 4
08028 Barcelona

I HEREBY BEG THE COURT to consider the above pleading for the opportune purposes.

FIFTH ADDITIONAL PLEADING, that at the time of filing this suit, my client did not yet have Spanish translations of documents 9, 35 and 36. This translation shall be presented as soon as this party receives it.

I HEREBY BEG THE COURT to consider the above pleading for the opportune purposes.

SIXTH ADDITIONAL PLEADING, that as the power of attorney attached is of a general nature for lawsuits,

I HEREBY BEG THE COURT to agree to register it and return it to this party, after entering it in the Minutes.

SEVENTH ADDITIONAL PLEADING, that in accordance with the terms of article 253 of Act 1/2000, this party hereby declares that the dimensions of the claim in this suit has not been determined and that the said claim does not affect the kind of suit applicable.

I HEREBY BEG THE COURT to consider the above pleading for the opportune purposes.

EIGHTH ADDITIONAL PLEADING, that this party has entrusted the legal direction of this proceeding to the Attorneys of the Illustrious Solicitors' Association of Madrid, Mr. Antonio Castán Pérez-Gómez (Member no. 24, 841) and Mr. Enrique Armijo Chávarri (Member no. 28, 816), both of whom have their professional offices in Madrid, at calle de Miguel Ángel no. 21 (Telephone: 91 700 94 00).

I HEREBY BEG THE COURT to consider the above pleading for the opportune purposes.

NINTH ADDITIONAL PLEADING, that in application of Art. 135.1 of the Civil Prosecution Act 1/2000, the attached writ that is subject to a deadline is presented before three o' clock in the afternoon of the working day following expiry of the deadline.

I HEREBY BEG THE COURT to consider the above pleading for the opportune purposes.

In witness whereof, I hereby request Justice in Madrid on the date of April 11th, 2005.

_____
Antonio Castán

Certificación

Don/doña Cristina Vega Becerro
Intérprete Jurado de Inglés
certifica que la que antecede es traducción fiel y completa del Inglés al Español de un documento redactado en Español
En Madrid a 28 Junio 2005

FIRMA

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